Complete Summary

GUIDELINE TITLE

Basic guidelines for diabetes care.

BIBLIOGRAPHIC SOURCE(S)

Diabetes Coalition of California, California Diabetes Prevention and Control Program. Basic guidelines for diabetes care. Sacramento (CA): California Diabetes Prevention and Control Program, Department of Health Services; 2003. 26 p.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT **CATEGORIES**

SCOPE

DISEASE/CONDITION(S)

Type 1 diabetes mellitus

IDENTIFYING INFORMATION AND AVAILABILITY

• Type 2 diabetes mellitus

GUIDELINE CATEGORY

Diagnosis Management Screening

CLINICAL SPECIALTY

Family Practice Internal Medicine Obstetrics and Gynecology Pediatrics

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Nurses Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- To present basic guidelines for diabetes care
- To update the 2002 version of these basic guidelines

TARGET POPULATION

Adults, children, and adolescents with type 1 and type 2 diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Physical and emotional assessment, including blood pressure, weight, height and body mass index (BMI) for age (for children), foot exam (for adults), dilated eye exams (by trained expert), screening for depression, dental exam
- 2. Laboratory examination, including hemoglobin A1c (A1C) measurement, microalbuminuria (albumin/creatinine ratio) assessment; blood lipids measurement (for adults)
- 3. Self-management training, including management principles and complications, self-glucose monitoring, medical nutrition therapy (physical activity, weight management)
- 4. Interventions, including preconception, pregnancy, and postpartum counseling and management, aspirin therapy, smoking cessation, immunizations (influenza, pneumococcal)

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Pertinent articles for review were identified from Medline searches, periodicals, and the reference lists from the previous year's Basic Guidelines for Diabetes Care.

NUMBER OF SOURCE DOCUMENTS

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Experts in diabetes care reviewed and rated the body of evidence using a system adopted from the American Diabetes Association (ADA) grading system for clinical practice recommendations. The system rates practice recommendations based on the level of evidence for the recommendation and the likelihood of clinical benefit. A is the highest rating and "expert consensus" is the lowest.

- A. Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:
 - Evidence from a well-conducted multi-center trial
 - Evidence from a meta-analysis that incorporated quality ratings in the analysis
 - Compelling non-experimental evidence, i.e. "all or none" rule developed by the Center for Evidence Based Medicine at Oxford

Supportive evidence from well-conducted randomized controlled trials that are adequately powered including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- B. Supportive evidence from well-conducted prospective cohort studies, including:
 - Evidence from a well-conducted prospective study or registry
 - Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case control study

- C. Supportive evidence from poorly controlled or uncontrolled studies
 - Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
 - Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
 - Evidence for case series or case report
 - Conflicting evidence with the weight of evidence supporting the recommendation
- D. Expert consensus or clinical experience

Diabetes Care, Vol 25, Supplement J, January 2002

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Physical and Emotional Assessment

Blood Pressure, Weight: Every visit. Blood pressure (BP) target goal <130/80 mmHg. For children: Add height, normal body mass index (BMI) for age, plot on 2001 Centers for Disease Control and Prevention (CDC) growth charts; blood pressure <90th percentile age standard.

Foot Exam (for adults): Thorough visual inspection every diabetes care visit; pedal pulses, neurological exam yearly.

Dilated Eye Exam (by trained expert): Type 1: Five years post diagnosis, then every year. Type 2: Shortly after diagnosis, then every year. Note: Internal quality assurance data may be used to support less frequent testing.

Depression: Probe for emotional/physical factors linked to depression yearly; treat aggressively with counseling, medication, and/or referral.

Dental: Exams at least twice yearly. Prophylaxis two to four times a year.

<u>Lab Exam</u>

A1C (Hemoglobin A1c): Quarterly, if treatment changes or if not meeting goals; One or two times/year if stable. Target goal <7.0% or <1% above lab norms. For children: Modify as necessary to prevent significant hypoglycemia.

Microalbuminuria (Albumin/Creatinine Ratio): Type 1: Begin with puberty once the duration of diabetes is more than five years unless proteinuria has been documented. Type 2: Begin at diagnosis, then every year unless proteinuria has been documented.

Blood Lipids (for adults): On initial visit, then yearly for adults. Target goals (mg/dL): cholesterol, triglycerides <200; low-density lipoproteins (LDL) <100; high-density lipoproteins (HDL) >45 for men; high-density lipoproteins >55 for women.

Self-Management Training

Management Principles and Complications: Initially and yearly: Assess knowledge of diabetes, medications, self-monitoring, acute/chronic complications, and problem-solving skills. Ongoing: Screen for problems with and barriers to self-care; assist patient to identify achievable self-care goals. For children: As appropriate for developmental stage.

Self-Glucose Monitoring: Type 1: Typically test four times a day. Type 2 and others: As needed to meet treatment goals.

Medical Nutrition Therapy (by trained expert): Initially: Assess needs/condition; assist patient in setting nutrition goals. Ongoing: Assess progress toward goals; identify problem areas.

Physical Activity: Initially and ongoing: Assess and prescribe physical activity based on patient's needs/condition.

Weight Management: Initially and ongoing: Must be individualized for patient.

<u>Interventions</u>

Preconception, Pregnancy, and Postpartum Counseling and Management: Consult with high-risk, multidisciplinary perinatal/neonatal programs and providers where available (e.g., California Diabetes and Pregnancy Program "Sweet Success"). For adolescents: Age appropriate counseling advisable, beginning with puberty.

Aspirin Therapy: 81 to 325 mg/day or 325 mg every other day in adults as primary and secondary prevention of cardiovascular disease, unless contraindicated.

Smoking Cessation: Screen, advise, and assist at every diabetes care visit, adjusting the frequency as appropriate to the patient's response.

Immunizations: Influenza and pneumococcal, per Centers for Disease Control and Prevention (CDC) recommendations.

Explanatory Notes

It is assumed that the following are routinely occurring in the medical setting:

- 1. A history and physical appropriate for a person with diabetes are performed. Visits are sufficiently frequent to meet the patient's needs and treatment goals.
- 2. Abnormal physical or laboratory findings result in appropriate and individualized interventions.
- 3. Self-management training is provided by multi-disciplinary health professionals who are experts in the provision of this training. For children/adolescents and their families, training from a diabetes team or team member with experience in child and adolescent diabetes is strongly recommended to begin at diagnosis.
- 4. Physicians should consult current references for normal values and for appropriate treatment goal values, both for children and adults.
- 5. Specialists should be consulted when patients are unable to achieve treatment goals in a reasonable time frame, when complications arise, or whenever the primary care physician deems it appropriate. Under similar circumstances, children/adolescents should be referred to specialists who have expertise in managing children and adolescents with diabetes.

Additional comments on specific items included in the guidelines:

Psychosocial assessment: Assess barriers to self-care: common environmental obstacles, cultural issues, beliefs and feelings about diabetes, disorders of eating and mood, life stresses, and substance use.

A1C (Hemoglobin A1c)/Self-Glucose Monitoring: Certification by the National Glycohemoglobin Standardization Program as traceable to the Diabetes Control Complications Trial (DCCT) reference ensures portability of A1C results. Verify that the laboratory is certified in this method. A1C target goals should be achieved gradually over time. Target goals should be less stringent for children, the elderly, and other fragile patients. Clinicians have found that making the patient aware of his/her A1C values and their significance helps motivate the patient toward improved glycemic control. This principle also applies to self-glucose monitoring. Target goals should be individualized for each patient.

Microalbuminuria: Screening is not needed if proteinuria has been documented. See Screening and Initial Management of Diabetic Microalbuminuria and Nephropathy algorithm in original guideline document.

Blood Lipids: Abnormal blood lipids are often under-treated. An active, progressive treatment and monitoring plan should be instituted.

Dental: Physicians are urged to recommend dental care as a part of basic diabetes care.

Children/Adolescents: For specific diabetes care recommendations see references in the original guideline document.

CLINICAL ALGORITHM(S)

The guideline contains clinical algorithms* for:

- Therapy for Glycemic Control of Type 2 Diabetes Mellitus in Adults
- Screening and Initial Management of Diabetic Microalbuminuria and Nephropathy
- Foot Care for People with Diabetes
- Gestational Diabetes (GDM) Screening, Diagnosis, and Management

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

An annotated bibliography, categorizing the references used to support the inclusion of specific items, is provided in the original guideline document. Each reference is rated according to the scheme listed above (see "Rating Scheme for the Strength of the Evidence"). In general, items in the guidelines are included based on one or more of the following criteria:

- Published evidence demonstrated either the efficacy or the effectiveness of the item.
- Published studies on cost-identification, cost-effectiveness, or cost-benefit analysis of the item demonstrated favorable economic results.
- A preponderance of expert opinion held that the item is considered to be essential to the care of persons with diabetes.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Prevention or delay of diabetic morbidity and mortality

POTENTIAL HARMS

None stated

^{*} These algorithms are adapted from the American Diabetes Association (ADA) Clinical Practice Recommendations, 2003

QUALIFYING STATEMENTS

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- These guidelines are intended for use by primary care professionals.
- These guidelines are meant to be basic guidelines, not enforceable standards.
- Internal quality assurance data may be used to support less frequent testing.
- These guidelines, developed by local and national diabetes experts, are consistent with American Diabetes Association Clinical Practice Recommendations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Staff from the Diabetes Prevention and Control Program meet with payors, providers, and managed care organizations statewide to implement these guidelines. Implementation is also encouraged through the California Cooperative Healthcare Reporting Initiative's (CCHRI) distribution of the guidelines to help change primary care provider practice.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Diabetes Coalition of California, California Diabetes Prevention and Control Program. Basic guidelines for diabetes care. Sacramento (CA): California Diabetes Prevention and Control Program, Department of Health Services; 2003. 26 p.

ADAPTATION

The algorithms that accompany the "Basic Guidelines for Diabetes Care" were adapted by the Diabetes Coalition of California (DCC) from the American Diabetes Association (ADA) Clinical Practice Recommendations, 2003.

DATE RELEASED

1999 Jan (revised 2003 Jan)

GUIDELINE DEVELOPER(S)

California Diabetes Prevention and Control Program - Private Nonprofit Organization

Diabetes Prevention and Control Program - Private Nonprofit Organization

SOURCE(S) OF FUNDING

Not stated

GUI DELI NE COMMITTEE

Diabetes Coalition of California Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Executive Committee: Rebecca Olson, PhD, Lumetra (Chair); Brenda Yamashita, Diabetes Program, Alameda County Public Health (Vice Chair); Irving L. Spratt, MD, FACP, Health Educators Medical Group (Immediate Past Chair); Gary Arsham, MD, PhD, FACP, California Pacific Medical Center (Treasurer); Rae Lee, RD, MPH, Perinatal Nutrition Consultant (Secretary)

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Diabetes Prevention and Control Program: Ann Albright, PhD, RD (Chief); Mark Shannon, PA, CDE (Interim Chief)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

American Diabetes Association - Professional Association Blue Cross of California State Sponsored Program - Managed Care Organization California Cooperative Healthcare Reporting Initiative - Professional Association Conference of Local Health Offices (California) - Independent Expert Panel Health Resource Services Administration Health Disparities Collaborative - Federal Government Agency [U.S.]

Hill Physicians Group - Professional Association

Lumetra - Professional Association

Medical Board of California - State/Local Government Agency [U.S.]

Pacific Business Group on Health - Private For Profit Organization

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Sacramento (CA): California Department of Health Services, Diabetes Control Program; 2002 Jan. Various p.

These guidelines are updated annually.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the California Diabetes Prevention and Control Program Web site.

Print copies: Available from the California Department of Health Services, Diabetes Prevention and Control Program, 1616 Capitol Avenue, MS 7211, PO Box 997413, Sacramento, CA 95899-7413; telephone, (916) 552-9888; fax, (916) 552-9888; Web site: www.caldiabetes.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available in Portable Document Format (PDF) from the <u>California Diabetes Prevention and Control Program Web site</u>:

- Diabetes Health Record, a self-management tool for patients available in 14 languages.
- Provider Fact Sheets: a series of simple fact sheets developed to help providers on a number of diabetes topics.

The following is also available:

 Professional Guidelines Presentation: a PowerPoint presentation developed for the medical professional to inform health care providers and organizations about the Basic Guidelines for Diabetes Care.

Print copies: Available from the California Department of Health Services, Diabetes Prevention and Control Program, 1616 Capitol Avenue, MS 7211, PO Box 997413, Sacramento, CA 95899-7413; telephone, (916) 552-9888; fax, (916) 552-9888; Web site: www.caldiabetes.org.

PATIENT RESOURCES

The following are available in Portable Document Format (PDF) from the <u>California Diabetes Prevention and Control Program Web site</u>:

 Patient/Consumer Fact Sheets: a series of simple fact sheets developed to help patients on a number of diabetes topics.

The following is also available:

 Take Charge! Presentation: a PowerPoint presentation developed for nonprofessionals to educate people with diabetes about the Basic Guidelines for Diabetes Care and how to use the Diabetes Health Record.

Print copies: Available from the California Department of Health Services, Diabetes Prevention and Control Program, 1616 Capitol Avenue, MS 7211, PO Box 997413, Sacramento, CA 95899-7413; telephone, (916) 552-9888; fax, (916) 552-9888; Web site: www.caldiabetes.org.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on January 10, 2000. The information was verified by the guideline developer as of January 31, 2000. This summary was updated July 9, 2001. This summary was updated again on October 23, 2002, and verified by the guideline developer on December 5, 2002. This summary was updated again on May 4, 2004. The updated information was verified by the guideline developer on July 20, 2004.

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